

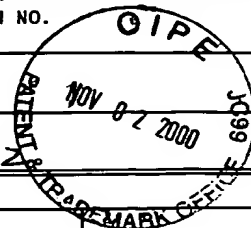
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FORM PTO-1449

## INFORMATION DISCLOSURE STATEMENT

ATTY. DOCKET NO.  
0609.4830001APPLICATION NO.  
09/617,116APPLICANT  
Aghi *et al.*FILING DATE  
July 14, 2000GROUP  
1632

## U.S. PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB-CLASS	FILING DATE
QN	AA1	5,529,774	06/25/1996	Barba <i>et al.</i>	424	93.21	08/13/1991
	AB1	5,591,624	01/07/1997	Barber <i>et al.</i>	435	240.2	11/23/1993
	AC1	5,601,818	02/11/1997	Freeman <i>et al.</i>	424	93.21	12/08/1994
	AD1	5,631,236	05/20/1997	Woo <i>et al.</i>	514	44	08/26/1993
	AE1	5,670,488	09/23/1997	Gregory <i>et al.</i>	514	44	10/13/1993
	AF1	5,688,773	11/18/1997	Chiocca <i>et al.</i>	514	44	10/28/1994
	AG1	5,691,177	11/25/1997	Guber <i>et al.</i>	435	172.3	06/05/1995
	AH1	5,741,486	04/21/1998	Pathak <i>et al.</i>	424	93.21	06/06/1995
↓	AI1	5,763,217	06/09/1998	Cynader <i>et al.</i>	435	69.1	10/11/1995
QN	AJ1	5,763,242	06/09/1998	Zhang <i>et al.</i>	435	172.3	02/08/1995
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EXAMINER INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION
QN	AL1	WO 95/06486	03/09/1995	WIPO			Yes No
	AM						Yes No
	AN						Yes No
	AO						Yes No
	AP						Yes No

## OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

QN	AR	1	Abdallah, B. <i>et al.</i> , "Non-viral gene transfer: Applications in developmental biology and gene therapy," <i>Biol. Cell</i> 85:1-7 (1995).
QN	AS	1	Aghi, M. <i>et al.</i> , "Synergistic Anticancer Effects of Ganciclovir/Thymidine Kinase and 5-Fluorocytosine/Cytosine Deaminase Gene Therapies," <i>J. Natl. Cancer Inst.</i> 90:370-380 (March 1998).
QN	AT	1	Aghi, M. <i>et al.</i> , "Folypolyglutamyl Synthetase Gene Transfer and Glioma Antifolate Sensitivity in Culture and <i>In Vivo</i> ," <i>J. Natl. Cancer Inst.</i> 91:1233-1241 (July 1999).

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FORM PTO-1449 INFORMATION DISCLOSURE STATEMENT				ATTY. DOCKET NO. 0609.4830001		TECH CENTER 1600/2399 09/617,116	
				APPLICANT Aghi et al.		NOV 02 2000 PATENT & TRADEMARK OFFICE	
				FILING DATE July 14, 2000			

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QN	AR	2	Aghi, M. et al., "Prodrug activation enzymes in cancer gene therapy," <i>J. Gene Med.</i> 2:148-164 (May-June 2000).
QN	AS	2	Barredo, J. and Moran, R.G., "Determinants of Antifolate Cytotoxicity: Folylpolyglutamate Synthetase Activity during Cellular Proliferation and Development," <i>Molec. Pharmacol.</i> 42:687-694 (1992).
QN	AT	2	Calos, M.P. et al., "The potential of extrachromosomal replicating vectors for gene therapy," <i>Trends in Genetics</i> 12:463-467 (1996).

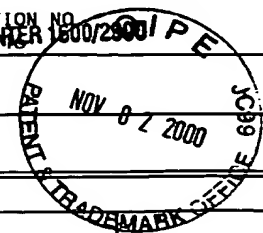
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				APPLICANT Aghi et al.			
				FILING DATE July 14, 2000			





  

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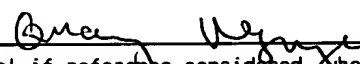
  

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	AN						Yes No
	AO						Yes No
	AP						Yes No

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)			
	AR	3	Chabner, B.A. et al., "Polyglutamation of Methotrexate," <i>J. Clin. Invest.</i> 76:907-912 (1985)
	AS	3	Chase, M. et al., "An oncolytic viral mutant that delivers the CYP2B1 transgene and augments cyclophosphamide chemotherapy," <i>Nature Biotechnol.</i> 16:444-448 (1998).
 	AT	3	Chen, L. and Waxman, D.J., "Intratumoral Activation and Enhanced Chemotherapeutic Effect of Oxazaphosphorines following Cytochrome P-450 Gene Transfer: Development of a Combined Chemotherapy/Cancer Gene Therapy Strategy," <i>Cancer Res.</i> 55:581-589 (1995).

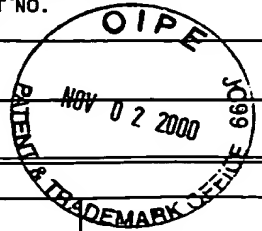
  

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APPROPRIATION NO.  
09/617,116

FORM PTO-1449

## INFORMATION DISCLOSURE STATEMENT

ATTY. DOCKET NO.  
0609.4830001APPLICANT  
Aghi et al.FILING DATE  
July 14, 2000GROUP  
1614

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	AM						Yes No
	AN						Yes No
	AO						Yes No
	AP						Yes No

## OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

QW	AR	4	Chu, E. and Allegra, C.J., "Antifolates," in <i>Cancer Chemotherapy and Biotherapy: Principles and Practice</i> , 2 <sup>nd</sup> Edition, Chabner, B.A. and Longo, D.L., eds., Lippincott-Raven Publishers, New York, NY, pp. 109-148 (1996).
↓	AS	4	Dachs, G.U. et al., "Targeting Gene Therapy to Cancer: A Review," <i>Oncol. Res.</i> 9:313-325 (1997).
↓	AT	4	Danks, M.K. et al., "Overexpression of a Rabbit Liver Carboxylesterase Sensitizes Human Tumor Cells to CPT-11," <i>Cancer Res.</i> 58:20-22 (January 1998).

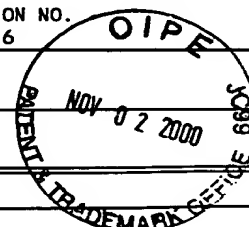
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AW	AR	5	Deonarain, M.P. <i>et al.</i> , "Genetic Delivery of Enzymes for Cancer Therapy," <i>Gene Therapy</i> 2: 235-244 (1995).
↓	AS	5	Drinkard, L. <i>et al.</i> , "A Phase II Trial of Edatrexate (ETX) in Progressive Malignant Glioma (PMG)," <i>Program/Proceedings of the American Soc. of Clinical Oncology</i> 13:182, Abstract No. 517 (1994).
↓	AT	5	Freeman, S.M. <i>et al.</i> , "The 'Bystander Effect': Tumor Regression When a Fraction of the Tumor Mass Is Genetically Modified," <i>Cancer Res.</i> 53:5274-5283 (1993).

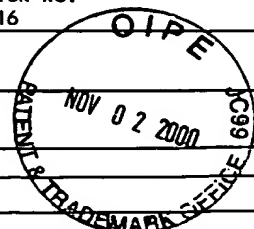
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	AN						Yes No
	AO						Yes No
	AP						Yes No

## OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

AW	AR	6	Freeman, S.M. <i>et al.</i> , "In Situ Use of Suicide Genes for Cancer Therapy," <i>Semin. Oncology</i> 23:31-45 (1996).
J	AS	6	Freemantle, S.J. and Moran, R.G., "Transcription of the Human Polyglutamate Synthetase Gene," <i>J. Biol. Chem.</i> 272:25373-25379 (1997).
↓	AT	6	Fry, D.W. <i>et al.</i> , "Analysis of the Role of Membrane Transport and Polyglutamation of Methotrexate in Gut and the Ehrlich Tumor <i>in Vivo</i> as Factors in Drug Sensitivity and Selectivity," <i>Cancer Res.</i> 43:1087-1092 (1983).

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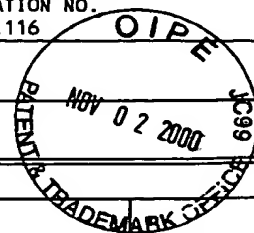
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TECH CENTER 1600/2500 of 18

FORM PTO-1449 <u>INFORMATION DISCLOSURE STATEMENT</u>	ATTY. DOCKET NO. 0609.4830001	APPLICATION NO. 09/617,116
	APPLICANT Aghi <i>et al.</i>	
	FILING DATE July 14, 2000	GROUP 1614



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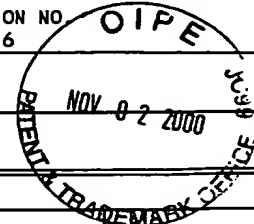
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	AM						Yes No
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	AO						Yes No
	AP						Yes No

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)			
QW	AR	Z	Garrow, T.A. <i>et al.</i> , "Expression cloning of a human cDNA encoding folylpoly( $\gamma$ -glutamate) synthetase and determination of its primary structure," <i>Proc. Natl. Acad. Sci. USA</i> 89:9151-9155 (1992).
I	AS	Z	Kim, J.-S. <i>et al.</i> , "Regulation of Folate and One-carbon Metabolism in Mammalian Cells," <i>J. Biol. Chem.</i> 268:21680-21685 (1993).
V	AT	Z	Lan, K-H. <i>et al.</i> , "In Vivo Selective Gene Expression and Therapy Mediated by Adenoviral Vectors for Human Carcinoembryonic Antigen-producing Gastric Carcinoma," <i>Cancer Res.</i> 57:4279-4284 (1997).

EXAMINER <i>Quay</i>	DATE CONSIDERED 08/24/01
EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.	

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	AM						Yes No
	AN						Yes No
	AO						Yes No
	AP						Yes No

## OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

QW	AR	8	Li, W.-W. <i>et al.</i> , "Mechanisms of Natural Resistance to Antifolates in Human Soft Tissue Sarcomas," <i>Cancer Res.</i> 52:1434-1438 (1992).
↓	AS	8	Matherly, L.H. <i>et al.</i> , "Antifolate Polyglutamylation and Competitive Drug Displacement at Dihydrofolate Reductase as Important Elements in Leucovorin Rescue in L1210 Cells," <i>Cancer Res.</i> 46:588-593 (1986).
↓	AT	8	McGuire, J.J. and Russell, C.A., "Folypolyglutamate Synthetase Expression in Antifolate-Sensitive and -Resistant Human Cell Lines," <i>Oncology Res.</i> 10:193-200 (1998).

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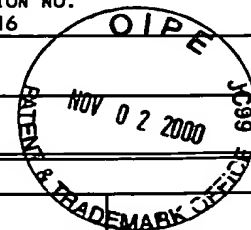
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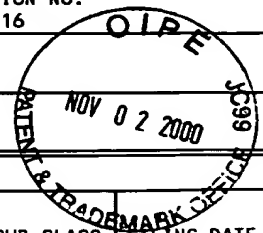
QW	AR	2	Miller, N. and Whelan, J., "Progress in Transcriptionally Targeted and Regulatable Vectors for Genetic Therapy," <i>Hum. Gene Ther.</i> 8:803-815 (1997).
↓	AS	2	Moolten, F.L., "Drug sensitivity ("suicide") genes for selective cancer chemotherapy," <i>Cancer Gene Ther.</i> 1:279-287 (1994).
↓	AT	2	Murdoch, B. <i>et al.</i> , "A rapid screening procedure for the identification of high-titer retrovirus packaging clones," <i>Gene Ther.</i> 4:744-749 (1997).

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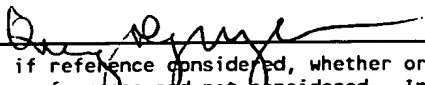

  

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	AO						Yes No
	AP						Yes No

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)			
QW	AR	10	Nakanishi, M. <i>et al.</i> , "Gene Introduction Into Animal Tissues," <i>Crit. Rev. Therapeut. Drug Carrier Systems</i> 12:263-310 (1995).
J	AS	10	O'Malley, Jr., B.W. <i>et al.</i> , "Combination Gene Therapy for Oral Cancer in a Murine Model," <i>Cancer Res.</i> 56:1737-1741 (1996).
V	AT	10	O'Malley, Jr., B.W. and Li, D., "Combination Gene Therapy for Salivary Gland Cancer," <i>Ann. N.Y. Acad. Sci.</i> 842:163-170 (April 1998).

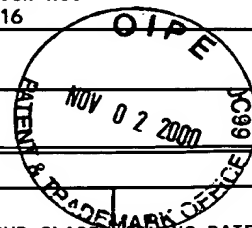
  

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	AP						Yes No

## OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

QW	AR	11	Peters, G.J. and van der Wilt, C.L., "Development of a Simple Polyglutamate Synthetase Assay in Tissues and Cell Lines," in <i>Chemistry and biology of Pteridines and Folates</i> , Ayling, J.E. et al., eds., Plenum Press, NY, pp. 651-654 (1993).
↓	AS	11	Pizzorno, G. et al., "Impaired Polyglutamylation of Methotrexate as a Cause of Resistance in CCRF-CEM Cells after Short-Term, High-Dose Treatment with This Drug," <i>Cancer Res.</i> 48:2149-2155 (1988).
↓	AT	11	Rainov, N.G. et al., "Retrovirus-Mediated Gene Therapy of Experimental Brain Neoplasms Using the Herpes Simplex Virus-Thymidine Kinase/Ganciclovir Paradigm," <i>Cancer Gene Therapy</i> 3:99-106 (1996).

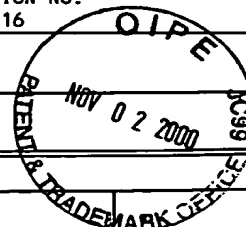
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AW	AR	12	Ram, Z. <i>et al.</i> , "In Situ Retroviral-mediated Gene Transfer for the Treatment of Brain Tumors in Rats," <i>Cancer Res.</i> 53:83-88 (1993).
V	AS	12	Rancourt, C. <i>et al.</i> , "Endothelial Cell Vehicles for Delivery of Cytotoxic Genes as a Gene Therapy Approach for Carcinoma of the Ovary," <i>Clin. Cancer Res.</i> 4:265-270 (February 1998).
V	AT	12	Robbins, P.D. <i>et al.</i> , "Viral vectors for gene therapy," <i>TIBTECH</i> 16:35-40 (January 1998).

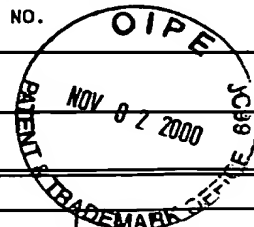
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ATTY. DOCKET NO.  
0609.4830001APPLICATION NO.  
09/617,116APPLICANT  
Aghi *et al.*FILING DATE  
July 14, 2000GROUP  
1614

## U.S. PATENT DOCUMENTS

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	AL						Yes No
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	AN						Yes No
	AO						Yes No
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## OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

aw	AR	13	Rogulski, K.R. <i>et al.</i> , "Glioma Cells Transduced with an <i>Escherichia coli</i> CD/HSV-1 TK Fusion Gene Exhibit Enhanced Metabolic Suicide and Radiosensitivity," <i>Human Gene Ther.</i> 8:73-85 (1997).
J	AS	13	Roth, J.A. <i>et al.</i> , "Retrovirus-Mediated Wild-Type p53 Gene Transfer to Tumors of Patients with Lung Cancer," <i>Nature Med.</i> 2:985-991 (1996).
J	AT	13	Roth, J.A. and Cristiano, R.J., "Gene Therapy for Cancer: What Have We Done and Where are we Going?" <i>J. Natl. Cancer Inst.</i> 89:21-39 (1997).

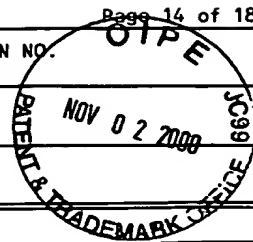
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QW	AR	14	Roy, K. <i>et al.</i> , "Different Antifolate-resistant L1210 Cell Variants with either Increased or Decreased Folylpolyglutamate Synthetase Gene Expression at the Level of mRNA Transcription," <i>J. Biol. Chem.</i> 270:26918-26922 (1995).
J	AS	14	Roy, K. <i>et al.</i> , "Posttranscriptionally Mediated Decreases in Folylpolyglutamate Synthetase Gene Expression in Some Folate Analogue-resistant Variants of the L1210 Cell," <i>J. Biol. Chem.</i> 272:6903-6908 (1997).
✓	AT	14	Rumberger, B.G. <i>et al.</i> , "Differing Specificities for 4-Aminofolate Analogues of Folylpolyglutamyl Synthetase from Tumors and Proliferative Intestinal Epithelium of the Mouse with Significance for Selective Antitumor Action," <i>Cancer Res.</i> 50:4639-4643 (1990).

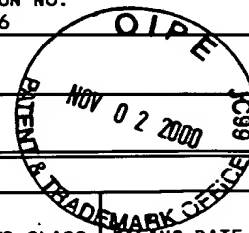
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OW	AR	15	Samuels, L.L. <i>et al.</i> , "Similar Differential for Total Polyglutamylation and Cytotoxicity among Various Folate Analogues in Human and Murine Tumor Cells <i>in Vitro</i> ," <i>Cancer Res.</i> 45:1488-1495 (1985).
	AS	15	Takemura, Y. and Jackman, A.L., "Folate-based thymidylate synthase inhibitors in cancer chemotherapy," <i>Anti-Cancer drugs</i> 8:3-16 (1997).
	AT	15	Takemura, Y. <i>et al.</i> , "Altered Expression of Folylpolyglutamate Synthetase (FPGS) Gene in Human Leukaemia Cells with Defective Polyglutamation of Raltitrexed (ZD1694)," <i>Brit. J. Cancer</i> 75(suppl. 1):31, Abstract No. P52 (1997).

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	AR	16	Taylor, S.M. <i>et al.</i> , "Structural Organization of the Human Folylpoly-γ-glutamate Synthetase Gene: Evidence for a Single Genomic Locus," <i>Cancer Res.</i> 55: 6030-6034 (1995).
	AS	16	Terzis, A.J.A. <i>et al.</i> , "Proliferation, Migration and Invasion of Human Glioma Cells Exposed to Antifolate Drugs," <i>Int. J. Cancer</i> 54:112-118 (1993).
	AT	16	Uckert, W. <i>et al.</i> , "Double Suicide Gene (Cytosine Deaminase and Herpes Simplex Virus Thymidine Kinase) but Not Single Gene Transfer Allows Reliable Elimination of Tumor Cells <i>In Vivo</i> ," <i>Human Gene Ther.</i> 9:855-865 (April 1998).

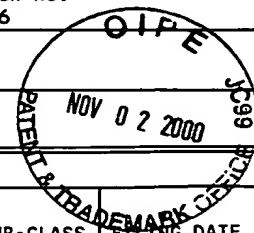
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	AR	17	Wei, M.X. <i>et al.</i> , "Experimental Tumor Therapy in mice Using the Cyclophosphamide-Activating Cytochrome P450 2B1 Gene," <i>Hum. Gene Ther.</i> 5:969-978 (1994).
	AS	17	Yu, J.S. <i>et al.</i> , "Retroviral Delivery and Tetracycline-dependent Expression of IL-1 $\beta$ -converting Enzyme (ICE) in a Rat Glioma Model Provides Controlled Induction of Apoptotic Death in Tumor Cells," <i>Cancer Res.</i> 56:5423-5427 (1996).
	AT	17	Zhang, J. and Russell, S.J., "Vectors for cancer gene therapy," <i>Cancer &amp; Metastasis Rev.</i> 15:385-401 (1996).

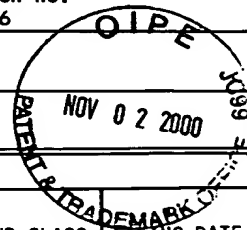
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QW	AR	18	Zufferey, R. <i>et al.</i> , "Multiply attenuated lentiviral vector achieves efficient gene delivery in vivo," <i>Nature Biotechnol.</i> 15:871-875 (1997).
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